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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/834,424

04/13/2001

Stuart L. Schreiber

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CHOATE, HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110

EXAMINER

VOGEL, NANCY TREPTOW

ART UNIT

PAPER NUMBER

1636

NOTIFICATION DATE

DELIVERY MODE

03/18/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@choate.com

Office Action Summary	Application No. 09/834,424	Applicant(s) SCHREIBER ET AL.	
	Examiner NANCY VOGEL	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons of record set forth in the Office actions mailed 5/29/09.

The Declaration of Clackson has been referenced in support of Applicants' arguments. Said declaration has been considered and addressed as part of the Applicants' arguments, as follows:

At page 10 of the amendment filed 20 November 2009, Applicants criticize the Connolly et al. reference for having failed to perform a control experiment to determine if the compounds they tested bound the EPO receptors in the cellular assay. However, it must be presumed that the workers who designed and carried out the experiments in Connolly et al., i.e., the authors thereof, were skilled in the relevant art. Their choice of the particular compounds to be tested reflects the state of the art at about the time of filing. Their alleged failure to determine whether the compounds in question bound in cellular assays or not, is actually off point. What is more significant to the question of the state of the art and predictability of the art, as it applies specifically to the written description requirement, and also the enablement requirement, discussed below, is that Connolly et al. selected these compounds based upon their knowledge and

understanding in the art to test, presumably with the expectation of succeeding in finding a useful dimerization agent. Their failure despite their level of knowledge and skill in the art is evidence that the general level of skill and knowledge in the art, in view of the unpredictable nature of the art, was not sufficient to have convinced one of skill that Applicants were in possession of the full scope of the claimed invention at the time of filing.

At page 10, Applicants argue that Connolly et al. made bad choices in designing the compounds to be tested. First, however, it is maintained that this merely extends the argument that the failure of Connolly et al. is evidence that the prevailing level of skill in the art was insufficient for one of skill to have known what design choices to make, and particularly that this was so due to the level of unpredictability of the art. Second, the assertion by Applicants that the design choices of Connolly et al. were "improvident" is not supported by a showing that the prior art was sufficiently developed that one of skill would have (or should have) known what the right choices were. In the last paragraph at page 10, Applicants argue further along this line, that Connolly et al failed to disclose the concentration of reagent, as well as other conditions, and may have been using wrong concentrations. However, again, this merely shows the undeveloped nature of the art, and the unpredictability of the art.

At page 11, Applicants argue that Qureshi et al. and Goldberg et al. better depict the state of the art contemporaneous with Connolly et al. However, the success achieved by Qureshi et al. and Goldberg et al. are essentially in proof-of-concept experiments. A large amount of study was devoted to solving the problem of obtaining a

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compound which exhibits the desired properties. It is not apparent from these disclosures that such experiments had risen to the level of routine in the art at the times they were published.

Thus, it is believed that the fact pattern in view of the Connolly et al. reference is different than that placed before the Board of Appeals in the '424 divisional application, and in view of this, one of skill in the art would not have been persuaded that Applicants were in possession of the full scope of the claimed invention at the time of filing.

Claims 8-29 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record set forth in the Office Actions mailed 5/29/09, 11/2/04, 10/1/02, 7/15/05 and 7/7/03..

Applicants rely on the arguments presented against the rejection under 35 USC § 112, first paragraph, for lack of adequate written description, discussed above. Accordingly for the reasons given above, the instant rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

NV
3/14/10

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